US009060853B2

(12) **United States Patent**
Roeder et al.

(10) **Patent No.: US 9,060,853 B2**
(45) **Date of Patent: *Jun. 23, 2015**

(54) **STENT AND STENT-GRAFT DESIGNS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/056,502**

(22) Filed: **Oct. 17, 2013**

(65) **Prior Publication Data**

US 2014/0039601 A1 Feb. 6, 2014

Related U.S. Application Data

(63) Continuation of application No. 13/450,702, filed on Apr. 19, 2012.

(60) Provisional application No. 61/480,107, filed on Apr. 28, 2011, provisional application No. 61/569,590, filed on Dec. 12, 2011.

(51) **Int. Cl.**
A61F 2/82 (2013.01)
A61F 2/07 (2013.01)
(Continued)

(52) **U.S. Cl.**
CPC ... ***A61F 2/07*** (2013.01); *A61F 2/82* (2013.01); ***A61F 2/915*** (2013.01); ***A61F 2/95*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61F 2/07; A61F 2/82
USPC 623/1.15–1.36
See application file for complete search history.

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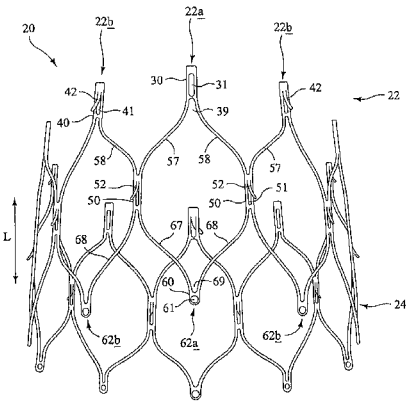
(57) **ABSTRACT**

The present embodiments provide stents and stent-grafts for use in medical procedures. In one embodiment, a stent comprises a series of proximal apices, a series of distal apices, and at least one imaging element. A first suture bore is disposed in a surface of the stent at a location distal to the imaging element, and is adapted to receive a suture for coupling a portion of the stent to a graft material. A distal region of the stent, including the series of distal apices and the first suture bore, overlaps with the graft material, while a proximal region of the stent, including the series of proximal apices and at least one barb, is disposed proximally beyond the graft material. In an alternative embodiment, a stent-graft comprises a graft, a first stent and a second stent, in which a series of proximal apices of the first stent are each disposed distal to the proximal end of the graft, and a series of proximal apices of the second stent are each disposed proximally beyond the proximal end of the graft.

17 Claims, 11 Drawing Sheets



(51) **Int. Cl.**

A61F 2/915	(2013.01)
A61F 2/95	(2013.01)
A61F 2/848	(2013.01)

(52) **U.S. Cl.**

CPC ... *A61F 2002/075* (2013.01); *A61F 2002/8483* (2013.01); *A61F 2002/8486* (2013.01); *A61F 2002/91575* (2013.01); *A61F 2002/9511* (2013.01); *A61F 2220/0075* (2013.01); *A61F 2220/0016* (2013.01); *A61F 2230/0013* (2013.01)

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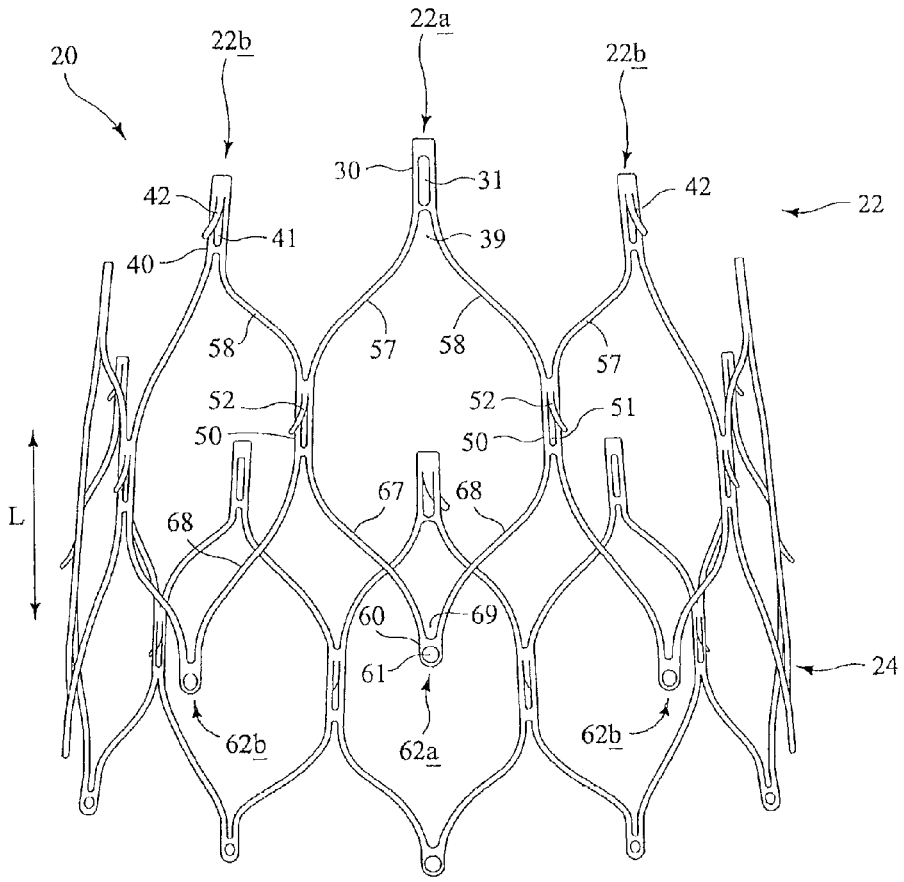
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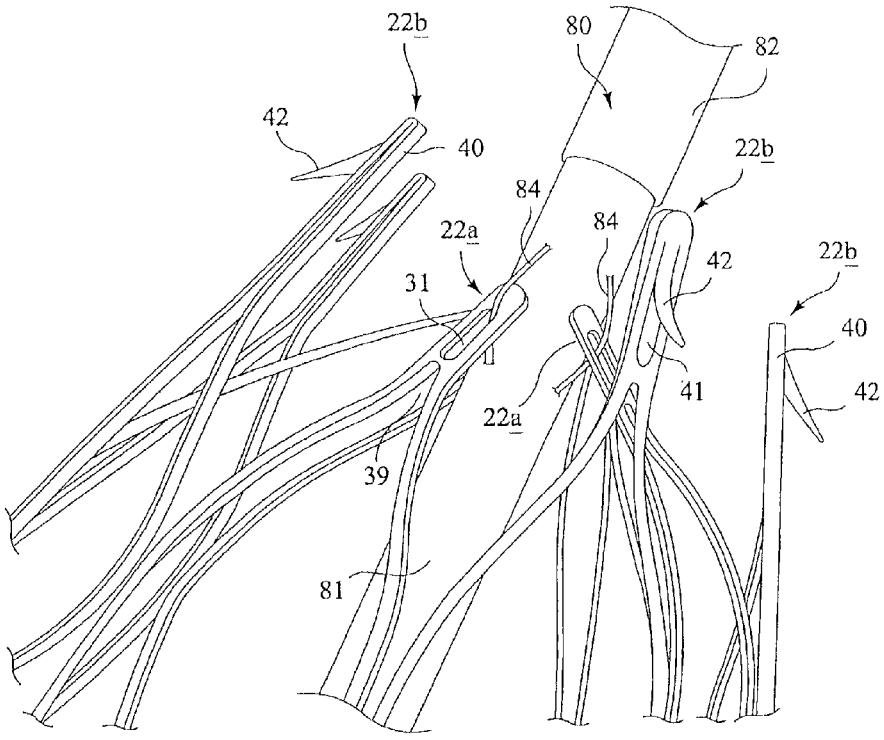
FIG. 1



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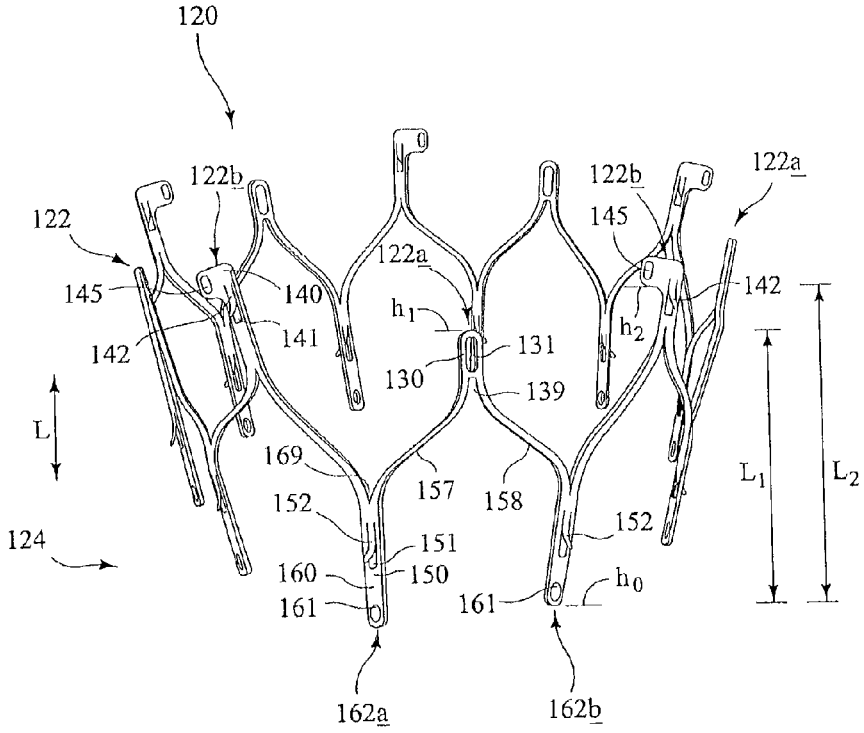
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FIG. 3

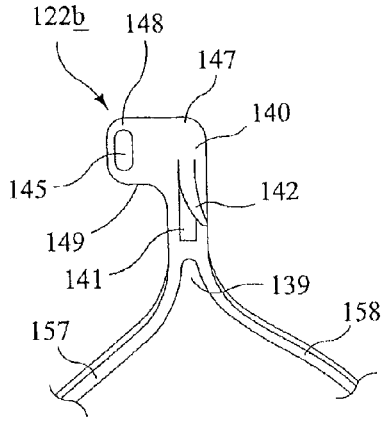
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FIG. 4

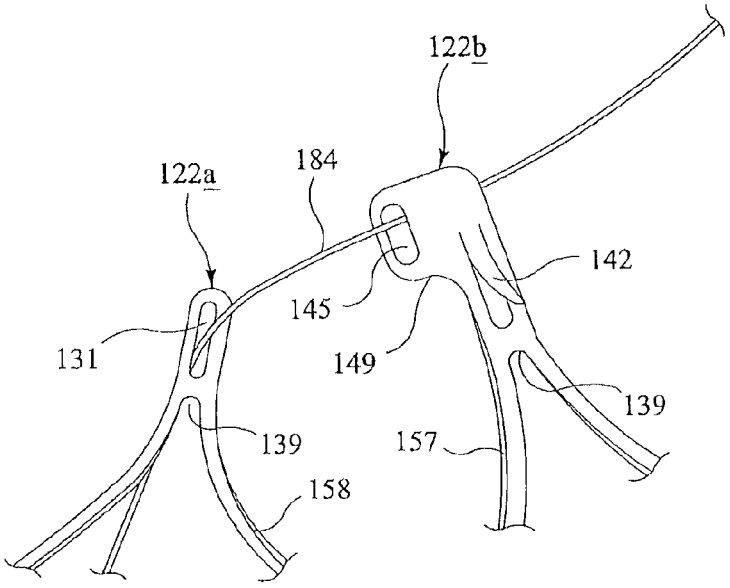
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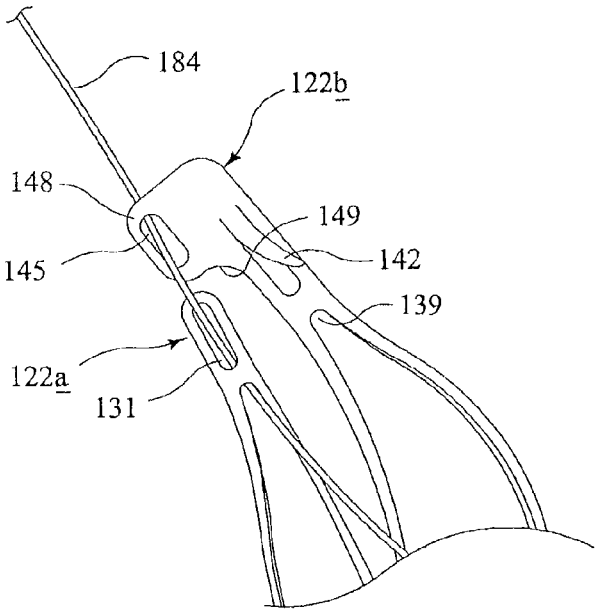
FIG. 5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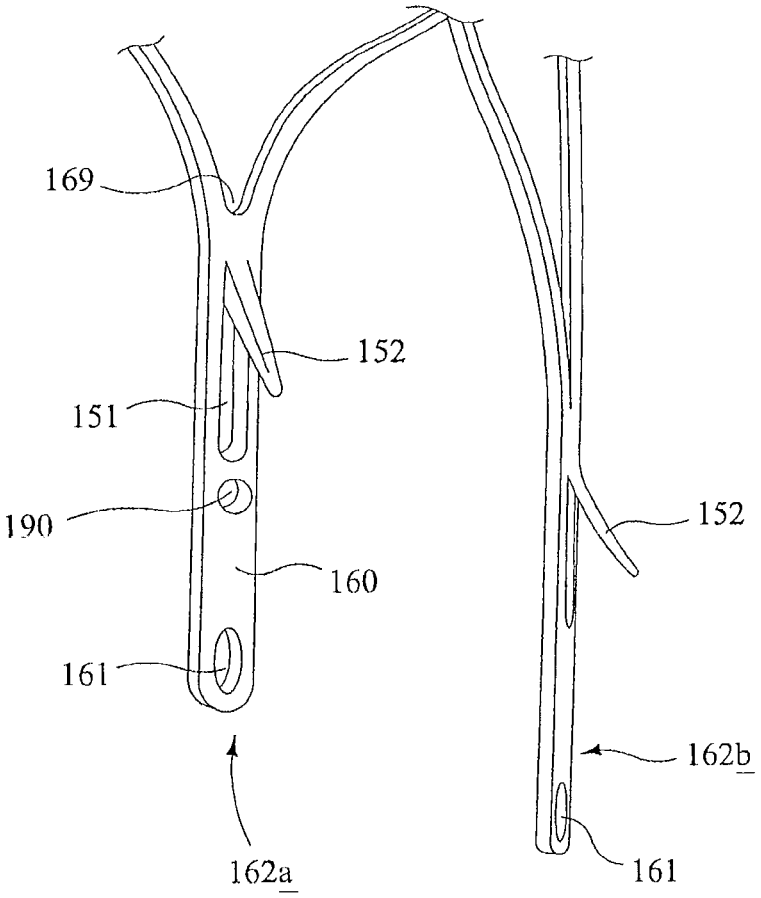

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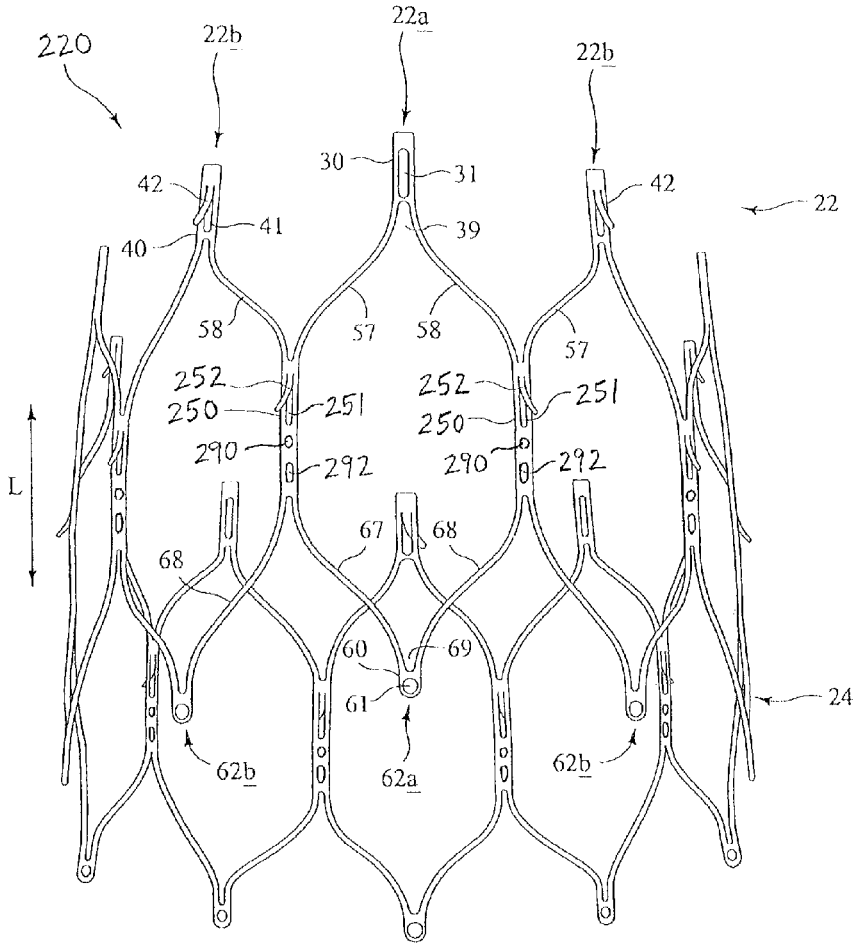
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FIG. 8

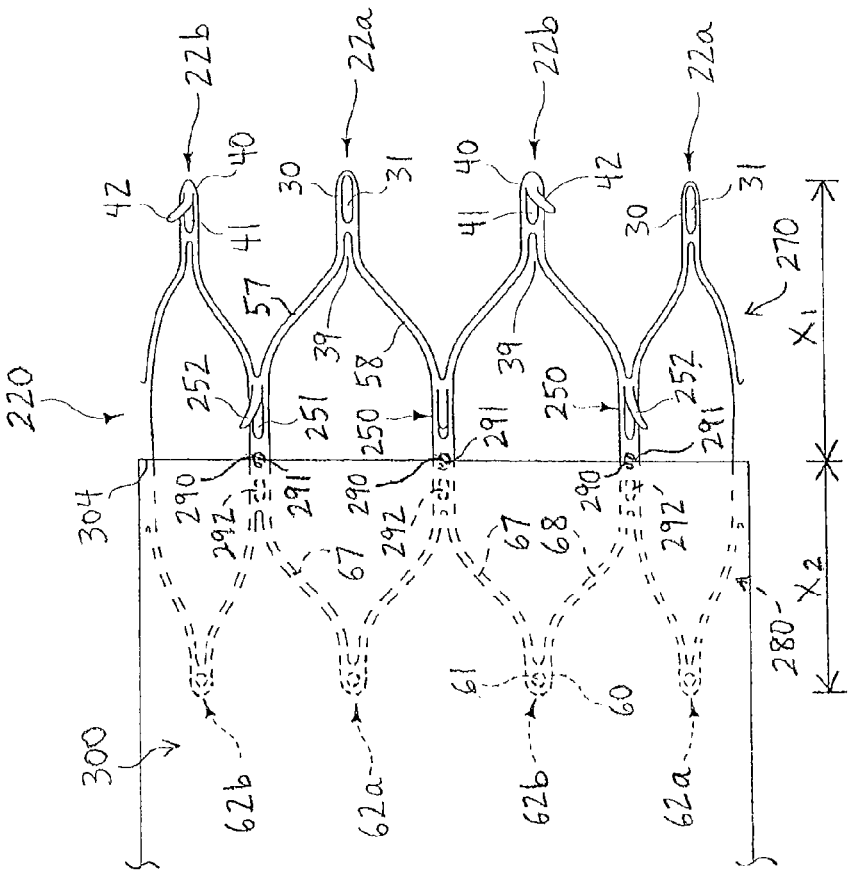
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FIG. 9

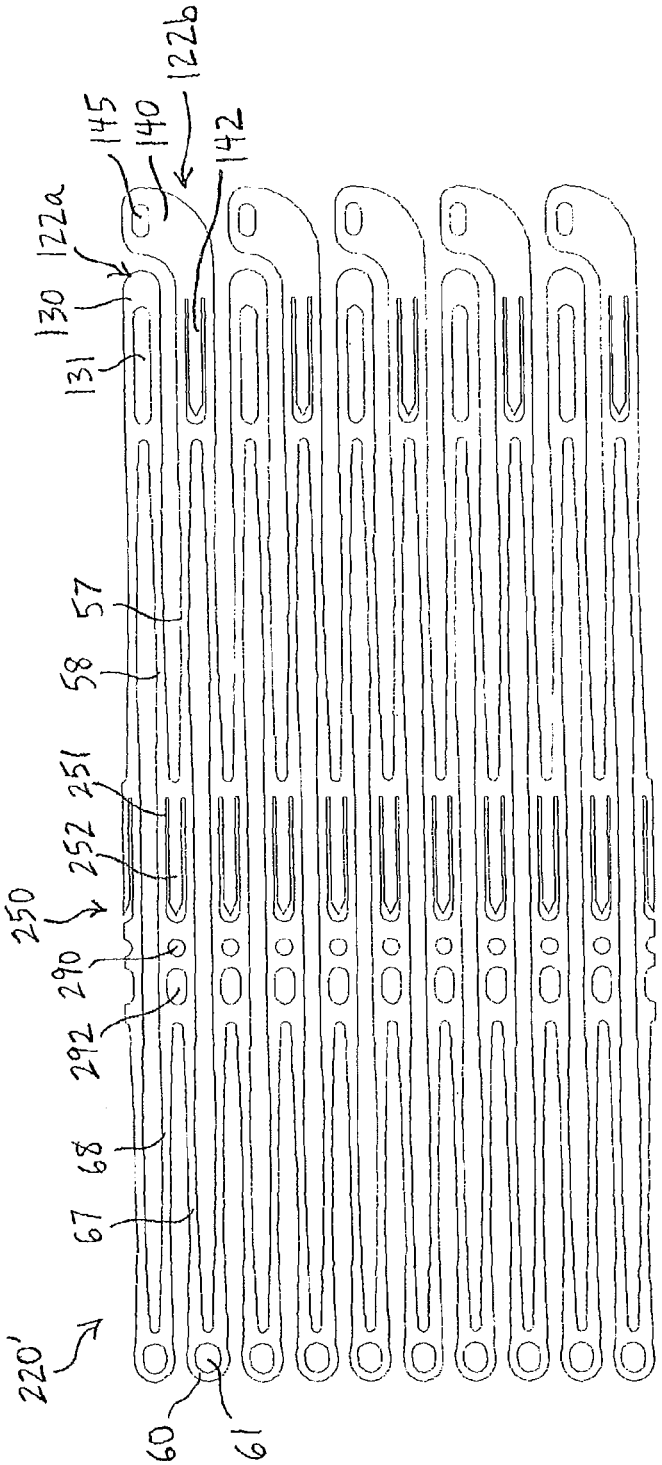
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FIG. 10

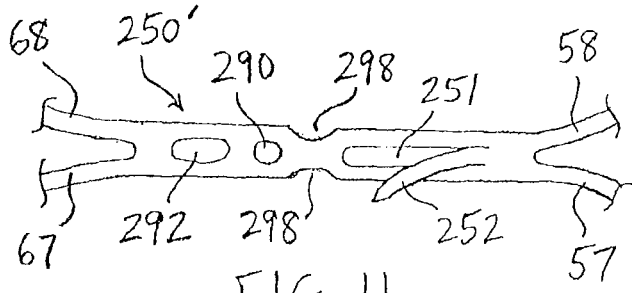

FIG. 11

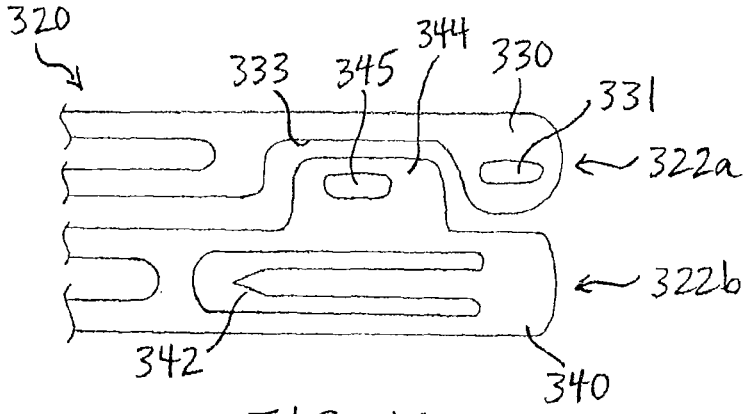

FIG. 12

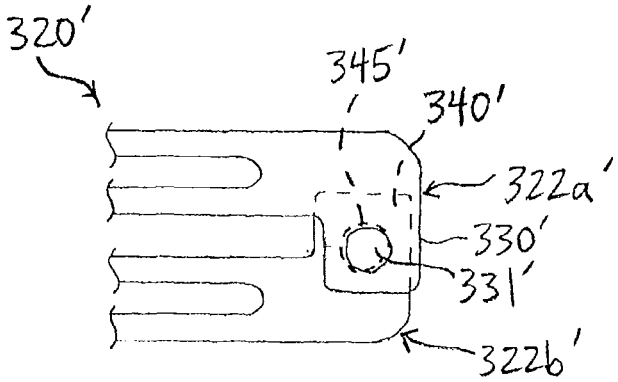

FIG. 13

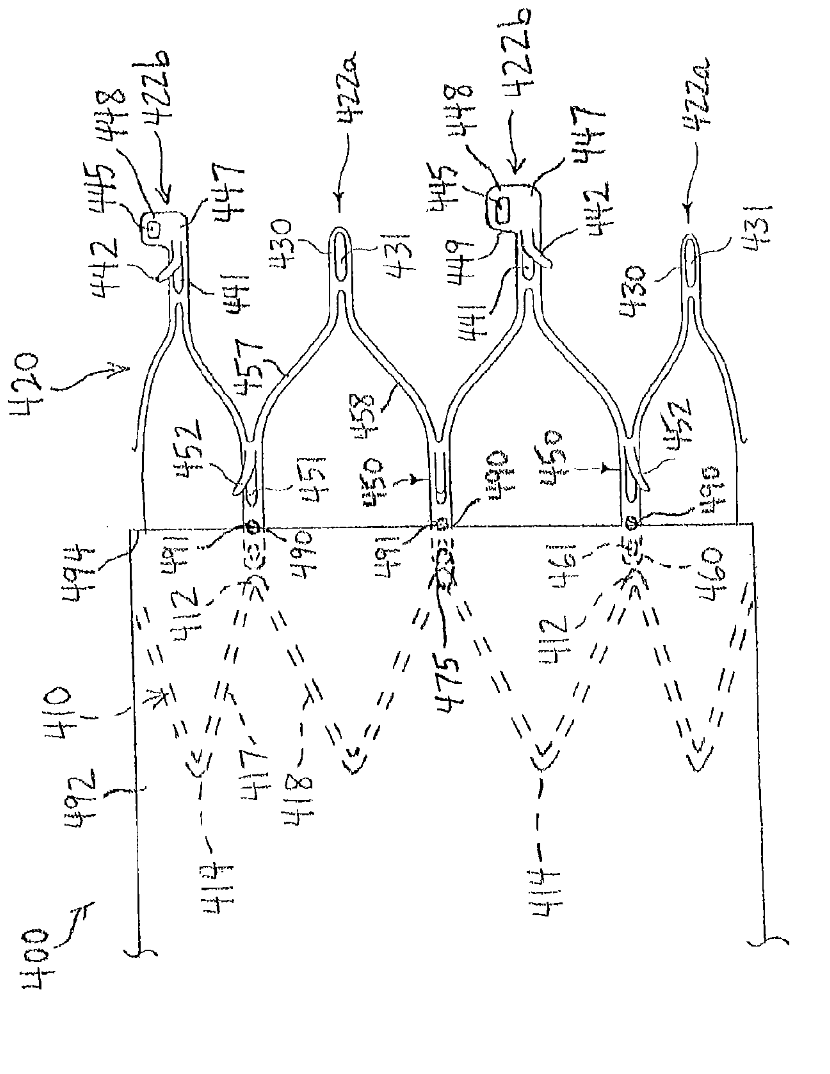
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FIG. 14

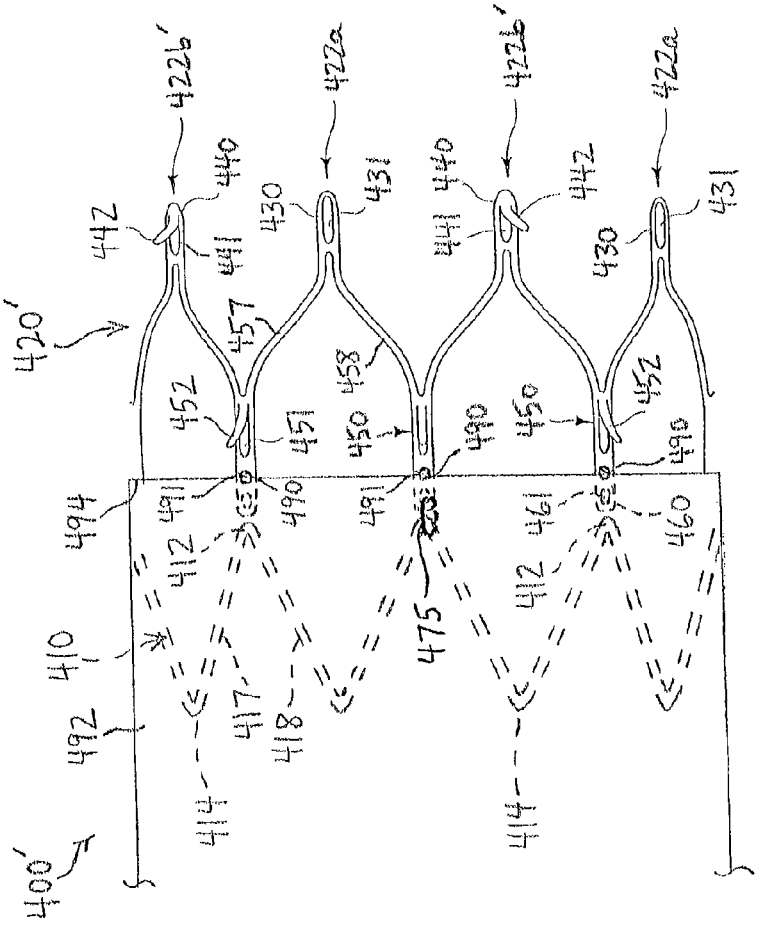
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FIG. 15

STENT AND STENT-GRAFT DESIGNS

PRIORITY CLAIMS

This application is a continuation of U.S. application Ser. No. 13/450,702 filed Apr. 19, 2012, which claims the benefit of priority of U.S. Provisional Application Ser. No. 61/480,107, entitled "Stent Designs For Use With One Or More Trigger Wires," filed Apr. 28, 2011, and also claims the benefit of priority of U.S. Provisional Application Ser. No. 61/569,590, entitled "Stent Designs For Use With One Or More Trigger Wires," filed Dec. 12, 2011, the disclosures of which are hereby incorporated by reference in their entireties.

BACKGROUND

The present embodiments relate generally to apparatus and methods for treating medical conditions, and more specifically, to stents and stent-grafts for use in body vessels to treat those medical conditions.

Stents may be inserted into an anatomical vessel or duct for various purposes. Stents may maintain or restore patency in a formerly blocked or constricted passageway, for example, following a balloon angioplasty procedure. Other stents may be used for different procedures, for example, stents placed in or about a graft have been used to hold the graft in an open configuration to treat an aneurysm. Additionally, stents coupled to one or both ends of a graft may extend proximally or distally away from the graft to engage a healthy portion of a vessel wall away from a diseased portion of an aneurysm to provide endovascular graft fixation.

Stents may be either self-expanding or balloon-expandable, or they can have characteristics of both types of stents. Self-expanding stents may be delivered to a target site in a compressed configuration and subsequently expanded by removing a delivery sheath, removing trigger wires and/or releasing diameter reducing ties. With self-expanding stents, the stents expand primarily based on their own expansive force without the need for further mechanical expansion. In a stent made of a shape-memory alloy such as nitinol, the shape-memory alloy may be employed to cause the stent to return to a predetermined configuration upon removal of the sheath or other device maintaining the stent in its predeployment configuration.

When trigger wires are used as a deployment control mechanism, the trigger wires may releasably couple the proximal and/or distal ends of a stent or stent-graft to a delivery catheter. Typically, one or more trigger wires are looped through a portion of the stent near a vertex of the stent. For example, trigger wires may be used to restrain a "Z-stent" or Gianturco stent comprising a series of substantially straight segments interconnected by a series of bent segments. The trigger wires may be disposed through, and pull upon, the bent segments to pull the stent closely against the delivery catheter.

Trigger wires also may be used in conjunction with different stent designs, such as cannula-cut stents having relatively acute or pointed bends. The designs of cannula-cut stents may facilitate compression of the stent to a relatively small delivery profile due to the tight bends of the apices. With such stents, the trigger wires may be looped around one or more vertices formed beneath the proximal and/or distal apices, e.g., a location where an individual apex splits into two separate strut segments.

If trigger wires are threaded through the vertices of such cannula-cut stents, the trigger wires may become crimped at the vertices during compression of the stent to a reduced diameter delivery profile. If the trigger wires are crimped between the strut segments, the trigger wires and/or stent segments may become damaged during delivery, particularly for nickel-titanium stents that may be sensitive to surface imperfections. Furthermore, when compressing a cannula-cut stent having relatively acute bends to a significantly reduced radial profile, barbs disposed near the apices of the stent may become entangled with the stent struts and/or the trigger wires.

SUMMARY

The present embodiments provide stents and stent-grafts for use in medical procedures.

In one embodiment, a stent for use in a medical procedure comprises a series of proximal apices disposed at a proximal end of the stent and a series of distal apices disposed at a distal end of the stent. A plurality of strut segments are disposed between the series of proximal apices and the series of distal apices, where the strut segments enable expansion of the stent from a compressed state to a deployed state. At least one barb is disposed at a location between the series of proximal apices and the series of distal apices. Further, an imaging element is disposed at a location distal to the at least one barb, and a first suture bore is disposed in a surface of the stent at a location distal to the imaging bore. A distal region of the stent, including the series of distal apices and the first suture bore, overlaps with a graft material, while a proximal region of the stent, including the series of proximal apices and the at least one barb, is disposed proximally beyond the graft material.

In one example, the distal region of the stent that overlaps with the graft material accounts for between about 20 to about 45 percent of the longitudinal length of the stent, while the proximal region that is disposed distally beyond the graft material accounts for between about 55 to about 80 percent of the longitudinal length of the stent. Further, the imaging bore may be disposed at the location corresponding to an endpoint of a proximal edge of the graft material.

In various embodiments, the stents described herein advantageously may reduce the number of trigger wires required during delivery, as a single trigger wire is not needed to restrain each individual apex. In one example, the series of proximal apices comprise alternating first and second proximal apices, where each of the first proximal apices comprises an end region having a first bore, and where each of the second proximal apices comprises a second bore, where at least one of the first proximal apices is simultaneously restrained with an adjacent, second proximal apex by a single trigger wire during delivery of the stent. The first bore formed in the first proximal apex may directly overlap with the second bore in the second proximal apex in a delivery state, where a single trigger wire is configured to be simultaneously disposed through the first and second bores.

In an alternative embodiment, a stent-graft for use in a medical procedure comprises a graft, a first stent and a second stent. The first stent has a plurality of strut segments disposed between a series of proximal and distal apices, and overlaps with the graft such that the series of proximal apices are each disposed distal to a proximal end of the graft. The second stent has a plurality of strut segments disposed between a series of proximal apices and a series of distal apices, where the series of distal apices of the second stent are each disposed distal to the proximal end of the graft, and the series of proximal apices of the second stent are each disposed proximally beyond the proximal end of the graft.

In various alternative embodiments, at least one of the proximal apices of the first stent may be circumferentially

aligned with a corresponding distal apex of the second stent. At least one of the proximal apices of the first stent may be sutured to one of the distal apices of the second stent. The first stent and the second stent may comprise different geometries.

Other systems, methods, features and advantages of the invention will be, or will become, apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended that all such additional systems, methods, features and advantages be within the scope of the invention, and be encompassed by the following claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention can be better understood with reference to the following drawings and description. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention. Moreover, in the figures, like referenced numerals designate corresponding parts throughout the different views.

FIG. **1** is a lower perspective view of an exemplary cannula-cut stent.

FIG. **2** is a perspective view illustrating the attachment of the stent of FIG. **1** to a delivery system.

FIG. **3** is an upper perspective view of another exemplary stent.

FIG. **4** is a perspective view illustrating features of a proximal apex of the stent of FIG. **3**.

FIG. **5** is a perspective view showing a trigger wire coupled to adjacent proximal apices of the stent of FIGS. **3-4**.

FIG. **6** is a perspective view showing the trigger wire of FIG. **5** holding the stent in a delivery configuration.

FIG. **7** is a perspective view showing a distal apex having a bore for receiving a radiopaque marker.

FIG. **8** is a lower perspective view of an alternative embodiment of a cannula-cut stent.

FIG. **9** is a side view of the stent of FIG. **8** coupled to a graft material.

FIG. **10** is a side view of an alternative stent in a flattened configuration.

FIG. **11** is a side view of a transition region of an alternative stent.

FIG. **12** is a side view illustrating features of proximal apices of an alternative stent.

FIG. **13** is a side view illustrating features of proximal apices of a further alternative stent.

FIG. **14** is of an embodiment of a stent-graft including first and second stents.

FIG. **15** is an alternative embodiment of the stent-graft of FIG. **14**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the present application, the term "proximal" refers to a direction that is generally closest to the heart during a medical procedure, while the term "distal" refers to a direction that is furthest from the heart during a medical procedure.

Referring to FIG. **1**, a stent **20** may be manufactured from a continuous cylinder into which a pattern may be cut by a laser or by chemical etching to produce slits in the wall of the cylinder. The resulting structure may then be heat set to give it a desired final configuration. The preferred final configuration includes a shape having a series of proximal apices and a series of distal apices, as generally shown in FIG. **1**. Therefore, the proximal end **22** of the stent **20** may comprise multiple adjacent proximal apices **22***a* and **22***b*, while the distal end **24** of the stent **20** may comprise multiple adjacent distal apices **62***a* and **62***b*, as shown in FIG. **1**.

In previously-known stents, one or more trigger wires may have been disposed through a vertex **39** at the proximal end **22** and/or through a vertex **69** at the distal end **24** of the stent. When the stent is compressed for delivery, if a trigger wire was disposed through the vertices **39** and **69**, the trigger wire may become pinched against the struts of the stent, which may damage the stent struts and/or the trigger wire itself. As explained below, the present embodiments utilize a different approach to coupling one or more trigger wires to the stent **20**.

Referring still to FIGS. **1-2**, at least one pair of adjacent, proximal apices **22***a* and **22***b* comprises different features. For example, as shown in FIG. **2**, a first proximal apex **22***a* may comprise an end region **30** having a bore **31** formed therein, wherein the bore **31** is configured to receive a trigger wire **84**. A second, adjacent proximal apex **22***b* comprises an end region **40** having an integral barb **42** formed therein, as shown in FIGS. **1-2**. However, the second proximal apex **22***b* is not configured to be restrained using a trigger wire, as explained and shown in FIG. **2** below. By using adjacent proximal apices **22***a* and **22***b* having the different features shown herein, an improved trigger wire attachment may be achieved and barb entanglement may be reduced, as explained further below.

As noted above, the stent **20** may comprise one or more barbs **42** disposed in at least one of the end regions **40** of the second proximal apices **22***b*. The barbs **42** may be formed by laser cutting a desired barb shape into the end regions **40**. A slit **41** therefore is formed into each end region **40** after the desired barb shape is formed, as shown in FIGS. **1-2**. Once the desired barb shape is cut, a main body of the barb **42** may be bent in a radially outward direction with respect to the end region **40**. The angle may comprise any acute angle, or alternatively may be substantially orthogonal or obtuse. If desired, the barbs **42** may be sharpened, for example, by grinding the tip of the barb, to facilitate engagement at a target tissue site.

Referring still to FIG. **1**, the stent **20** may comprise at least one strut segment disposed between the proximal and distal apices. For example, multiple angled strut segments may be disposed between a first proximal apex **22***a* and a corresponding distal apex **62***a*, and an identical set of angled strut segments may be disposed between an adjacent, second proximal apex **22***b* and a corresponding distal apex **62***b*. By way of example, the first proximal apex **22***a* extends distally and splits into first and second angled strut segments **57** and **58**, respectively, thereby forming a proximal vertex **39**, as shown in FIG. **1**. In a compressed state, the first and second angled strut segments **57** and **58** may be compressed such that they are substantially parallel to one another. In the expanded state shown in FIG. **1**, the first and second angled strut segments **57** and **58** are disposed an angle relative to a longitudinal axis L of the stent **20**. In the expanded state, the first and second angled strut segments **57** and **58** may be disposed at an angle of about 20-60 degrees relative to the longitudinal axis L of the stent **20**, as depicted in FIG. **1**.

Similarly, each distal apex **62***a* may extend in a proximal direction and splits into first and second angled strut segments **67** and **68**, respectively, thereby forming a distal vertex **69**. The first angled strut segments **57** and **67** of the proximal and distal apices **22***a* and **62***a*, respectively, may meet with the second angled strut segments **58** and **68** of the adjacent proximal and distal apices **22***b* and **62***b*, respectively, thereby forming a transition region **50**. In this manner, the stent **20** may be formed into a continuous, generally cylindrical shape, as shown in FIG. **1**.

Expansion of the stent **20** is at least partly provided by the angled strut segments **57**, **58**, **67** and **68**, which may be substantially parallel to one another in a compressed state, but may tend to bow outward away from one another in the expanded state shown in FIG. **1**. As explained further below, the stent **20** may be formed from any suitable material, and preferably a laser-cut nitinol cannula. If manufactured from nitinol, the stent **20** may assume the expanded state shown in FIG. **1** upon removal of a delivery sheath.

Each transition region **50** may be oriented in a direction that is substantially parallel to the longitudinal axis L of the stent **20**, as shown in FIG. **1**. Further, each transition region **50** may comprise a larger surface area relative to the angled segments, since the transition regions may be composed substantially of multiple different angled segments **57**, **58**, **67** and **68** meeting at a central location.

Referring still to FIG. **1**, the stent **20** may comprise at least one barb **52** disposed in at least one of the transition regions **50**. The barb **52** may be formed integrally, as part of the strut, or may comprise an external barb that is adhered to a surface of the transition regions **50**. Preferably, as shown in FIG. **1**, multiple integral barbs **52** are provided. The barbs **52** may be formed by laser cutting a desired barb shape into the transition regions **50**. In this manner, the barbs are monolithic with the transition region **50**. A slit **51** therefore is formed into the transition region **50** after the desired barb shape is formed, as shown in FIG. **1**. Since the transition regions **50** may comprise an increased surface area relative to other regions of the stent **20**, it may be easier to perforate portions of the transition regions **50** without adversely affecting the structural integrity of the stent. Once the desired barb shape is cut, a main body of the barb **52** may be bent in an outward direction at any angle with respect to the transition region **50** and optionally may be sharpened to facilitate engagement at a target tissue site.

Each of distal apices **62***a* and **62***b* may comprise an end region **60** having a bore **61** formed therein, as shown in FIG. **1**. The distal end **24** of the stent **20** may be coupled to a proximal end of graft material, such as the graft material **300** of FIG. **9** below. The distal apices **62***a* and **62***b* may be coupled to the graft material, for example, using one or more sutures that are looped through the graft material and the bores **61** of the stent **20**. In this manner, the stent **20** may be used as an attachment stent for endovascular graft fixation. For example, the graft material may overlap with an aneurysm to seal off fluid flow into the aneurysm, while the proximal end **22** of the stent **20** may extend in a proximal direction away from the graft material, e.g., to engage a healthy portion of a vessel wall away from a diseased portion of the aneurysm.

The stent **20** has a reduced diameter delivery state so that it may be advanced to a target location within a vessel or duct. The stent **20** also has an expanded deployed state to apply a radially outward force upon at least a portion of a vessel or duct, e.g., to maintain patency within a passageway, or to hold open the lumen of a graft. In the expanded state, fluid flow is allowed through a central lumen of the stent **20**. Further, the struts of the stent **20** may comprise a substantially flat wire profile or may comprise a rounded profile. As best seen in FIG. **2**, the struts of the stent **20** generally comprise a flat wire profile.

The stent **20** may be manufactured from a super-elastic material. Solely by way of example, the super-elastic material may comprise a shape-memory alloy, such as a nickel titanium alloy (nitinol). If the stent **20** comprises a self-expanding material such as nitinol, the stent may be heat-set into the desired expanded state, whereby the stent **20** can assume a relaxed configuration in which it assumes the preconfigured first expanded inner diameter upon application of a certain cold or hot medium. Alternatively, the stent **20** may be made from other metals and alloys that allow the stent **20** to return to its original, expanded configuration upon deployment, without inducing a permanent strain on the material due to compression. Solely by way of example, the stent **20** may comprise other materials such as stainless steel, cobalt-chrome alloys, amorphous metals, tantalum, platinum, gold and titanium. The stent **20** also may be made from non-metallic materials, such as thermoplastics and other polymers.

Referring now to FIG. **2**, the stent **20** may be delivered to a target site in a compressed configuration using a pushing member **80** and a plurality of trigger wires **84**. In FIG. **2**, the exemplary pushing member **80** comprises a main body **81** and a tapered region **82**, which is disposed proximal to the main body **81**. The tapered region **82** may subsequently transition into a smaller diameter at a proximal location, such that the relatively small diameter proximal region allows for atraumatic access and delivery. The plurality of trigger wires **84** may be disposed within the confines of the main body **81**, and may span the length of the pushing member **80**. The triggers wires **84** also may be activated by manipulating one or more handles, with optional locking features, to control deployment of the proximal end **22** of the stent **20**.

A single trigger wire **84** may be looped through the bore **31** of selected ones of the first proximal apices **22***a* to restrain the stent **20** during delivery. Trigger wires are not coupled to the second proximal apices **22***b*, which comprise the barbs **42**. In the embodiment shown, the trigger wires **84** are only disposed through alternating proximal apices, as seen in FIG. **2**. By restraining selected ones of the first proximal apices, such as each first proximal apex **22***a*, the adjacent second proximal apices **22***b* also may be indirectly pulled in a radially inward direction during delivery. The configuration of the stent **20**, and in particular the angled segments **57**, **58**, **67** and **68** that meet up at transition regions **50**, facilitates the indirect compression of the adjacent second proximal apices **22***b*. Advantageously, since only selected ones of the proximal apices are restrained during delivery, the number of trigger wires may be reduced. Moreover, since the barbs **42** are only disposed on every other apex, barb entanglement may be reduced or eliminated, as depicted in FIG. **2**.

Another advantage associated with the design of the stent **20** is that the trigger wires **84** are only disposed through the bores **31** of the first proximal apices **22***a*, as opposed to being disposed through the vertices **39**. Therefore, the trigger wires **84** may be less likely to become damaged during compression of the stent **20**. Further, the stent struts themselves are less likely to become damaged since the trigger wires **84** are isolated within the bores **31** of the first proximal apices **22***a*.

Referring now to FIGS. **3-6**, an alternative stent design is described. In FIG. **3**, stent **120** also may be manufactured from a continuous cylinder into which a pattern may be cut by a laser or by chemical etching to produce slits in the wall of the cylinder. The resulting structure may thereafter be heat set to give it a desired final configuration. The preferred final configuration includes a shape having a series of proximal apices and a series of distal apices, as generally shown in FIG. **3**. Therefore, the proximal end **122** of the stent **120** may comprise multiple adjacent proximal apices **122***a* and **122***b*, while the distal end **124** of the stent **20** may comprise multiple adjacent distal apices **162***a* and **162***b*, as shown in FIG. **3**.

One or more pairs of adjacent, proximal apices **122***a* and **122***b* may comprise different features. For example, a first proximal apex **122***a* may comprise an end region **130** having

a first bore **131** formed therein, wherein the first bore **131** is configured to receive a trigger wire **184**, as shown in FIGS. **5-6** below. A second, adjacent proximal apex **122***b* comprises an end region **140** having an integral barb **142** formed therein, as shown in FIGS. **3-6**. The second proximal apex **122***b* further comprises a second bore **145** formed therein, as best seen in FIG. **4**, which is configured to receive the same trigger wire **184** as the adjacent first proximal apex **122***a*, as explained and shown with respect to FIGS. **5-6** below. By using adjacent proximal apices **122***a* and **122***b* having the different features shown herein, an improved trigger wire attachment may be achieved and barb entanglement may be reduced, as explained further below.

Each of the second proximal apices **122***b* may comprise first and second regions **147** and **148**, as shown in FIG. **4**. A single barb **142** may be disposed in each of the second proximal apices **122***b* generally in the first region **147**, while the second bore **145** may be disposed generally in the second region **148**, as shown in FIG. **4**. The barbs **142** may be formed by laser cutting a desired barb shape into the end regions **140**, thereby forming a slit **141**, as generally explained with respect to the stent **20** hereinabove. Once the desired barb shape is cut, a main body of the barb **142** may be bent in a radially outward direction and optionally may be sharpened, as generally set forth above.

The second proximal apices **122***b* further may comprise a recessed portion **149** formed at a location distal to the second bore **145**, as best seen in FIG. **4**. As will be explained further below, during delivery of the stent **120**, the first proximal apex **122***a* is configured to be pulled towards the second proximal apex **122***b* and may become nested within the recessed portion **149** of the second proximal apex **122***b* when a trigger wire is disposed through the first and second bores **131** and **145**.

The first bores **131** of the first proximal apices **122***a* may be disposed slightly distal to the second bores **145** of an adjacent, second proximal apex **122***b*. Further, a first longitudinal distance L_1 between a distal edge h_0 of the stent **120** and a proximal edge h_1 of each proximal apex **122***a* may be less than a second longitudinal distance L_2 between the distal edge h_0 of the stent and a distal edge h_2 of each recessed portion **149**, as shown in FIG. **3**. This length differentiation may facilitate nesting of the first proximal apices **122***a* within the recessed portions **149** of the second proximal apices **122***b* during delivery of the stent, as explained further below with respect to FIGS. **5-6**.

Referring still to FIG. **3**, the stent **120** may comprise at least one strut segment disposed between the proximal and distal apices. In one configuration, the proximal and distal apices are not directly aligned with one another. For example, as shown in FIG. **3**, a first angled segment **157** may be disposed between a proximal apex **122***a* and a corresponding distal apex **162***a*, and a second angled segment **158** may be disposed between the same proximal apex **122***a* and an adjacent distal apex **162***b*. In effect, each proximal apex **122***a* and **122***b* extends distally and splits into the first and second angled strut segments **157** and **158**, respectively, thereby forming a proximal vertex **139**. Similarly, each distal apex **162***a* and **162***b* extends proximally and splits into the first and second angled strut segments **157** and **158**, respectively, thereby forming a distal vertex **169**. In this manner, the stent **120** may be formed into a continuous, generally cylindrical shape, as shown in FIG. **3**.

In a compressed state, the first and second angled strut segments **157** and **158** may be compressed such that they are substantially parallel to one another. In the expanded state shown in FIG. **3**, the first and second angled strut segments **157** and **158** may be disposed at an angle relative to a longitudinal axis L of the stent **120**, as shown in FIG. **3**. In the expanded state, the first and second angled strut segments **157** and **158** may be disposed at an angle of about 20-60 degrees relative to the longitudinal axis L of the stent **120**. Expansion of the stent **120** is at least partly provided by the angled strut segments **157** and **158**, which may be substantially parallel to one another in a compressed state, but may tend to bow outward away from one another in the expanded state shown in FIG. **3**. Like the stent **20** noted above, the stent **120** may be formed from any suitable material, and preferably a nickel-titanium alloy, so that it may assume the expanded state shown in FIG. **3** upon removal of a delivery sheath.

The first and second angled strut segments **157** and **158** meet with one another distally to form a distal transition region **150**, which effectively is the same as the distal end region **160** of the stent **120**. Each end region **160** may be oriented in a direction that is substantially parallel to the longitudinal axis L of the stent **120**, as shown in FIG. **3**. Further, each end region **160** may comprise a larger surface area relative to the angled segments, since the end regions **160** are composed substantially of multiple different angled segments **157** and **158** meeting up together. At least one distal barb **152** may be formed integrally by laser cutting a desired barb shape, thereby forming a slit **151** into the end region **160**, as shown in FIG. **3**. Since the end regions **160** may comprise an increased surface area relative to other regions of the stent **120**, it may be easier to perforate portions of the end regions **160** without adversely affecting the structural integrity of the stent. Further, a suture bore **161** may be formed in the end regions **160** of each of the distal apices **162***a* and **162***b*, as shown in FIG. **3**. The distal end **124** of the stent **120** may be coupled to a proximal end of graft material, such as the graft material **300** of FIG. **9** below, by looping the suture through the bore **161** and the graft material, as generally explained above with respect to the embodiment of FIGS. **1-2**.

Referring now to FIGS. **5-6**, the stent **120** may be delivered to a target site in a compressed configuration using a pushing member, such as pushing member **80** of FIG. **2**, and a plurality of trigger wires. In accordance with one aspect, a trigger wire **184** may be looped through the first bore **131** of each first proximal apex **122***a*, and further looped through the second bore of an adjacent, second proximal apex **122***b*. Therefore, each individual trigger wire may restrain two separate, adjacent proximal apices during delivery. When the stent **120** is fully compressed, as depicted in FIG. **6**, the adjacent first and second proximal apices **122***a* and **122***b* may be pulled closer together in the circumferential direction. Due to the difference between lengths L_1 and L_2, each proximal apex **122***a* may become nested substantially within the recessed portion **149** distal to the second region **148** of the proximal apex **122***b*, as shown in FIG. **6**. Further, the first bore **131** may be positioned distal to the second bore **145**, such that the first and second bores **131** and **145** are disposed substantially in longitudinal alignment with one another when the single trigger wire **184** is disposed through the first and second bores during delivery of the stent.

Advantageously, one single trigger wire may be used to restrain two separate, adjacent apices of the stent **120**. Further, the trigger wires **184** are only disposed through the bores **131** and **145**, but not disposed around the vertices **139**, and therefore the trigger wires may be less likely to become damaged during compression of the stent **120**. Further, the stent struts themselves are less likely to become damaged since the trigger wires **184** are isolated within the bores **131** and **145**.

Referring now to FIG. **7**, one or more of the distal apices **162***a* and **162***b* optionally may comprise an imaging bore **190**, which may be disposed between the suture bore **161** and the barb slit **151**. The imaging bore **190** may receive any suitable radiopaque marker, such as a gold marker. Preferably, the imaging bores **190** and associated radiopaque markers are provided on alternating distal apices, e.g., only distal apices **162***a*. Alternatively, the imaging bores **190** may be disposed on each distal apex **162***a* and **162***b*, or disposed on every third or fourth apex around the perimeter of the stent. The imaging bores **190** may be beveled, or alternatively, may be substantially orthogonal to the strut of the end region **160**.

In use, the imaging bores **190** may be aligned with the distal edge of a graft material, for example, when the stent **120** is used for endovascular graft fixation. More specifically, the suture bore **161** overlaps with a proximal region of the graft material, thereby allowing a suture to couple the stent **120** to the graft material with some desired degree of overlap. The proximal edge of the graft material therefore may be aligned with the imaging bores **190**. Advantageously, a physician may know exactly where the proximal edge of the graft material is being placed because he or she can view the position of the radiopaque markers in the imaging bores **190**. Therefore, the chances of inadvertently overlapping the graft material with a branch vessel, or another undesired location, may be reduced.

Referring now to FIGS. **8-9**, an alternative stent **220** is shown and described. The stent **220** is similar to the stent **20** of FIGS. **1-2**, with main exceptions noted below, and reference numbers of the stent **220** correspond to like reference numbers of the stent **20**.

The stent **220** comprises a transition region **250**, where the first angled strut segments **57** and **67** of the proximal and distal apices **22***a* and **62***a*, respectively, may meet with the second angled strut segments **58** and **68** of the adjacent proximal and distal apices **22***b* and **62***b*. Like the stent **20** of FIGS. **1-2**, the stent **220** comprises at least one barb **252** disposed in at least one of the transition regions **250**. As noted above with regard to the transition regions **50**, the barb **252** of the transition regions **250** may be formed integrally, as part of the strut, or may comprise an external barb that is adhered to a surface of the transition regions **250**. Preferably, as shown in FIG. **1**, multiple integral barbs **252** are provided, e.g., by laser cutting a desired barb shape and forming slits **251** into the transition regions **250**.

Additionally, the transition regions **250** of FIGS. **8-9** comprise an imaging bore **290** and a first suture bore **292**. The imaging bore **290** of the transition region **250** is disposed distal to the barb **252**, and in turn, the first suture bore **292** is disposed distal to the imaging bore **290**, as shown in FIGS. **8-9**.

Like the imaging bore **190** described in FIG. **7** above, the imaging bore **290** may receive any suitable radiopaque marker, such as an imaging element **291**, e.g., in the form of a gold marker, as depicted in FIG. **9**. The imaging bores **290** with the imaging element **291** disposed therein align with a proximal edge **304** of a graft material **300**, as shown in FIG. **9**, thereby allowing for precise imaging of the proximal edge **304**. Preferably, the imaging bores **290** and associated imaging elements **291** are provided on each of the transition regions **250**, as shown in FIGS. **8-9**. Therefore, in the example of FIGS. **8-9** where ten different transition regions **250** are provided between the proximal and distal apices, then ten different imaging bore **290** and corresponding imaging elements **291** are provided at the proximal edge **304** of the graft material **300**, thereby allowing for significantly enhanced visualization at the proximal edge **304**, particularly when the stent **220** is used for endovascular graft fixation.

The first suture bore **292** overlaps with a proximal region of the graft material **300**, thereby allowing a suture to couple the stent **220** to the graft material **300** with some desired degree of overlap. The proximal edge **304** of the graft material **300** therefore may be aligned with the imaging bores **290**, as noted above.

In the embodiment of FIGS. **8-9**, due to the provision of the first suture bore **292** in the transition region **250**, the bore **61** formed in the end region **60** of the distal apices **62***a* and **62***b* becomes a second suture bore. In other words, the graft material **300** is secured to the stent **220** via a suture disposed through the first suture bore **292**, and additionally is secured to the stent **220** via a suture disposed through the second suture bore **61**. A distal portion of the stent **220** therefore is secured to the graft material **300** at multiple spaced-apart longitudinal positions.

In the embodiment of FIGS. **8-9**, the stent **220** overlaps with the graft material **300** in a manner such that the stent **220** is capable of performing functions previously performed by two separate stents. Specifically, the design of the stent **220** and its manner of overlap with the graft material **300** allows the stent **220** to perform both a sealing function for the proximal end of the graft material **300**, and additionally to perform a bare attachment function to a vessel.

In particular, the stent **220** comprises a proximal region **270**, including the series of proximal apices **22***a* and **22***b* and a proximal portion of the transition region **250** including the at least one barb **252**, which spans a length x_1 and is disposed proximally beyond the graft material **300**, as shown in FIG. **9**. The stent **220** also comprises a distal region **280** including the series of distal apices **62***a* and **62***b* and a distal portion of the transition region **250** including the first suture bore **292**, which spans a length x_2 and overlaps with the graft material **300**. Notably, the imaging bore **290** with the corresponding imaging element **291** is disposed at a location corresponding to an endpoint of the proximal edge **304** of the graft material **300**.

In one embodiment, the length x_1 of the proximal region **270** of the stent **220** that disposed proximally beyond the graft material **300** accounts for between about 55 to about 80 percent of the longitudinal length of the stent **220**, while the length x_2 of distal region **280** of the stent that disposed within the graft material **300** accounts for between about 20 to about 45 percent of the longitudinal length of the stent.

Advantageously, the proximal region **270** of the stent **220** may be used as an attachment stent portion for endovascular graft fixation, while the distal region **280** of the stent **220** overlaps with the graft material **300** a sufficient distance to perform a sealing function for the proximal end of the graft **300**. This eliminates the need to provide a first stent at the proximal end of the graft material to provide a sealing function for the graft material **300** and a separate, substantially bare second stent attached at the most proximal end of the graft material **300** and extending proximally therefrom to perform an endovascular fixation function.

The stent **220** of FIGS. **8-9**, which eliminates the need for separate proximal graft sealing and bare vessel attachment stents, is particularly suitable and advantageous in treatment of thoracic or abdominal aortic aneurysms where there is a compromised anatomy allowing for a relatively short stent attachment zone at a proximal location. The stent **220** may be used with neck lengths (i.e., a sealing zone of the healthy tissue disposed between compromised tissue and/or side vessels) of between about 10 mm to about 15 mm. The stent **220** also may be used with neck angles up to about 45 degrees when disposed superior to the renal arteries and neck lengths up to about 60 degrees when disposed inferior to the renal

arteries. The stent **220**, when overlapping the proximal end of a graft material **300** as shown, therefore is able to "land" in a neck region of a patient's anatomy that is relatively short and angled, and where previous devices that utilized two separate stents at the proximal end of a graft material could not "land" without overlapping compromised tissue and/or side vessels. Additionally, the stent **220**, providing both graft sealing and bare attachment functions, may provide a higher radial force upon a vessel relative to separate sealing and bare attachment stents.

In one embodiment, the graft material **300** may comprise one or more stents coupled to distal and central regions of the graft material **300**, i.e., at locations distal to the stent **220**. The one or more stents coupled to distal and central regions of the graft material **300** may comprise a zig-zag shape formed from a single bent wire, or other desired shapes, thereby maintaining patency along a longitudinal length of the graft material **300** at locations distal to the stent **220**.

Referring now to FIG. **10**, an alternative stent **220'** is similar to the stent **220** of FIGS. **8-9**, with a main exception that the proximal region of the stent **220'** comprises the alternating proximal apices **122***a* and **122***b* of FIGS. **3-6**. Thus, the stent **220'** of FIG. **10**, like the stent **120** of FIGS. **3-6** above, permits a single trigger wire **184** to be disposed through the first and second bores **131** and **145** of adjacent proximal apices **122***a* and **122***b*, respectively.

Referring now to FIG. **11**, in an alternative embodiment, the stents **220** or **220'** of FIGS. **8-10** may further comprising a notched region **298** of reduced diameter disposed in an alternative transition region **250'** between the imaging bore **290** and the at least one barb **252**. The notched region **98** facilitates radial flaring of the proximal region **270** of the stents **220** and **220'**, thereby allowing the proximal apices to securely engage a vessel wall. While an exemplary notched region **298** is shown in FIG. **11**, alternative structures may be used to promote flaring of the proximal **270** radially outward relative to the distal region **280**.

Referring now to FIGS. **12-13**, alternative arrangements of proximal apices of a stent **320**, which may reduce the number of trigger wires in accordance with the principles above, are shown and described. In FIG. **12**, one or more pairs of adjacent, proximal apices **322***a* and **322***b* may comprise different features. For example, a first proximal apex **322***a* may comprise an end region **330** having a first bore **331** formed therein, wherein the first bore **331** is configured to receive the trigger wire **184** of FIGS. **5-6** above. A second, adjacent proximal apex **322***b* comprises an end region **340** having an integral barb **342** formed therein, as shown in FIG. **12**. The second proximal apex **322***b* further comprises a protruding region **344** having a second bore **345** formed therein, which is configured to receive the same trigger wire **184** as the adjacent first proximal apex **322***a*, in the manner described and shown with respect to FIGS. **5-6** above.

The first proximal apices **322***a* further may comprise a recessed portion **333** formed at a location distal to the first bore **331**, as shown in FIG. **12**. During delivery of the stent **320**, the second proximal apex **322***b* is configured to be pulled towards the first proximal apex **322***a*, such that the protruding region **344** of the second proximal apex **322***b* may become nested within the recessed portion **333** of the first proximal apex **322***a* when the trigger wire **184** of FIGS. **5-6** is disposed through the first and second bores **331** and **345**. The first and second bores **331** and **345** are disposed substantially in longitudinal alignment with one another when the single trigger wire **184** is disposed through the first and second bores **331** and **345** during delivery of the stent. Advantageously, by using adjacent proximal apices **322***a* and **322***b* having the different features shown herein, an improved trigger wire attachment may be achieved and barb entanglement may be reduced, as explained above.

Referring to FIG. **13**, a stent **320'** having one or more pairs of adjacent proximal apices **322***a'* and **322***b'* may comprise generally symmetrical features. The proximal apices **322***a'* comprise an end region **330'** having a first bore **331'** formed therein, while the distal apices **322***b'* comprise an end region **340'** having a second bore **345'** formed therein. The end regions **330'** and **340'** comprise protrusions, in which the first and second bores **331'** and **345'** are disposed, and where the protrusions generally face each other. Therefore, during delivery of the stent **320'**, the second proximal apex **322***b'* is configured to be pulled towards the first proximal apex **322***a'*, such that the protrusions of the first and second proximal apices **322***a'* and **322***b'* overlap, and in turn, the first and second bores **331'** and **345'** directly overlap as shown in FIG. **13**. Therefore, the trigger wire **184** of FIGS. **5-6** may be disposed through the first and second bores **331'** and **345'**.

Referring now to FIGS. **14-15**, alternative embodiments are shown and described. In FIG. **14**, stent-graft **400** comprises first and second stents **410** and **420** and a graft **492**. The graft **492** has proximal and distal ends and a lumen extending therebetween, though for illustrative purposes only the proximal end **494** of the graft **492** is shown in FIGS. **14-15**.

The first stent **410** has proximal and distal ends, a series of proximal apices **412** disposed at the proximal end of the first stent **410**, a series of distal apices **414** disposed at the distal end of the first stent **410**. A plurality of strut segments **417** and **418** are disposed between the series of proximal apices **412** and the series of distal apices **414** of the first stent **410**, as shown in FIGS. **14-15**. The first stent **410** overlaps with the graft **492** along a longitudinal length between the proximal and distal ends of the first stent **410**, such that the series of proximal apices **412** of the first stent **410** are each disposed distal to the proximal end **494** of the graft **492**, as shown in FIGS. **14-15**.

The second stent **420** has proximal and distal ends, a series of proximal apices **422***a* and **422***b* disposed at the proximal end of the second stent **420**, and a series of distal apices **460** disposed at the distal end of the second stent **420**. A plurality of strut segments **457** and **458** are disposed between the series of proximal apices **422***a* and **422***b* and the series of distal apices **460** of the second stent **420**, as shown in FIGS. **14-15**. The series of distal apices **460** of the second stent **420** are each disposed distal to the proximal end **494** of the graft **492**, and the series of proximal apices **422***a* and **422***b* of the second stent **420** are each disposed proximally beyond the proximal end **494** of the graft **492**.

At least one of the proximal apices **412** of the first stent **410** may be circumferentially aligned with a corresponding distal apex **460** of the second stent **420**. In one embodiment, each of the proximal apices **412** of the first stent **410** is circumferentially aligned with a corresponding distal apex **460** of the second stent **420**, as depicted in FIGS. **14-15**.

At least one of the proximal apices **412** of the first stent **410** may be coupled to one of the distal apices **460** of the second stent **420** by a suture **475**, as shown in FIGS. **14-15**. In one embodiment, each of the proximal apices **412** of the first stent **410** is sutured to a corresponding one of the distal apices **460** of the second stent **420** using a suture **475**. The suture **475** may be disposed through a portion of the graft **492**, thereby simultaneously coupling one of the proximal apices **412** of the first stent **410** to one of the distal apices **460** of the second stent **420** and also to the graft **492**. If desired, multiple sutures **475** may be used to couple the adjacent stents together, or one suture **475** may be used to couple the adjacent stents together

while one or more separate sutures are used to couple the stents **410** and **420** to the graft **492**.

In the embodiment of FIGS. **14-15**, the first stent **410** and the second stent **420** may comprise different geometries. In a non-limiting example, the first stent **410** comprises a zig-zag stent shape as shown in FIGS. **14-15**. In contrast, the second stent **420** of FIG. **14** has features of a stent that are similar to those described with respect to the stent **120** of FIGS. **3-6** above. In particular, the second stent **420** has a plurality of alternating first and second proximal apices **422***a* and **422***b*, where each of the first proximal apices **422***a* comprises an end region **430** having a first bore **431**. Each of the second proximal apices **422***b* may comprise first and second regions **447** and **448**, as shown in FIG. **14**. A single barb **442** may be disposed in each of the second proximal apices **422***b* generally in the first region **447**, while a second bore **445** may be disposed generally in the second region **448**, as shown in FIG. **14**. The barbs **442** may be formed by laser cutting a desired barb shape into the end regions, thereby forming a slit **441**, as generally explained with respect to the stent **120** hereinabove. Once the desired barb shape is cut, a main body of the barb **442** may be bent in a radially outward direction and optionally may be sharpened, as generally set forth above. The second proximal apices **422***b* further may comprise a recessed portion **449** formed at a location distal to the second bore **445**. As generally explained above with respect to the embodiment of FIGS. **3-6**, during delivery of the stent **420**, the first proximal apex **422***a* is configured to be pulled towards the second proximal apex **422***b* and may become nested within the recessed portion **449** of the second proximal apex **422***b* when a trigger wire is disposed through the first and second bores **431** and **445**.

The first and second angled strut segments **457** and **458** meet with one another distally to form a distal transition region **450**. In the embodiment of FIGS. **14-15**, each of the distal apices **460** of the second stent **420** comprises a suture bore **461** adapted to receive a suture for coupling the distal end of the second stent **420** to the graft **492**. Further, the suture bore **461** may be used to couple the distal end of the second stent **420** to the proximal end of the first stent **410** via a suture **475**, as noted above.

Further, each of the distal apices **460** of the second stent **420** may comprise an imaging bore **490** adapted to receive a radiopaque marker **491**. As described with respect to the embodiment of FIGS. **7** and **9** above, the imaging bore **490** is disposed proximal to the suture bore **461**, and the imaging bore **490** is adapted to be aligned with the proximal end **494** of the graft **492**, thereby allowing the imaging element **491** associated with the imaging bore **490** to significantly enhance imaging directly at the proximal end **494** of the graft **492**. Further, the second stent **420** may comprises at least one barb **452** that is integrally formed along the distal transition region **450**.

In FIG. **15**, an alternative stent-graft **400'** is similar to the stent-graft **400** of FIG. **14**, with a main exception that an alternative second stent **420'** comprises alternating first and second proximal apices **422***a* and **422***b'*. Each of the first proximal apices **422***a* comprises the end region **430** having the bore **431** as described in FIG. **14**, while each of the second proximal apices **422***b'* comprises at least one barb **442** for engaging tissue in a manner described above with respect to the embodiment of FIGS. **1-2**.

In each of the embodiments of FIGS. **14-15**, by having separate first and second stents **410** and **420**, bending and flexibility along the proximal region of the device may be enhanced while not compromising sealing and attachment functions. It has been unexpectedly found that by placing adjacent stents **410** and **420** in the manner shown in FIGS. **14-15**, particularly with one or more apices aligned with one another, that the flexibility of the stents relative to one another can be increased as opposed to decreased. The use of a suture **475** to couple apices of adjacent stents together may further provide an increased flexibility of the adjacent stents **410** and **420** relative to one another. Accordingly, due to the enhanced flexibility in the embodiments of FIGS. **14-15**, the stent-grafts **400** and **400'** may be useful for accommodating highly angulated and shorter aneurysm necks, thereby increasing the number of patients that can be treated. Moreover, the designs of FIGS. **14-15** are expected to reduce infolding along the proximal region of the device and promote enhanced stability when positioned within a bodily lumen.

While various embodiments of the invention have been described, the invention is not to be restricted except in light of the attached claims and their equivalents. Moreover, the advantages described herein are not necessarily the only advantages of the invention and it is not necessarily expected that every embodiment of the invention will achieve all of the advantages described.

We claim:

1. A prosthesis comprising:

a substantially tubular graft having a first end, a second end, a first edge at the first end, and a second edge at the second end, each of the first and second edges defining a periphery about the end of the graft;

an expandable stent attached to the graft at one of the ends of the substantially tubular graft, and having a first end, a second end, and a plurality of apices at the second end, each apex having a surface;

a suture bore disposed through the surface of each of the plurality of apices of the second end of the stent, the suture bore disposed inwardly of an edge of the graft;

an imaging bore disposed through the surface of each of the plurality of apices of the second end of the stent, the imaging bore disposed directly axially adjacent the suture bore;

an imaging element disposed in each imaging bore and having an area;

wherein each imaging element is aligned precisely with one of the first and second edges of the graft such that the area of the imaging element overlaps edge of the graft and the location of the imaging element corresponds precisely with the edge of the graft with which it is aligned and provides precise imaging of the edge about the periphery.

2. The prosthesis of claim **1**, wherein the first edge of the graft is a proximal edge of the graft and the second edge of the graft is a distal edge of the graft, and the first stent end is a proximal end of the stent and the second stent end is a distal stent end.

3. The prosthesis of claim **2**, where the imaging element is aligned precisely with the proximal edge of the graft.

4. The prosthesis of claim **1**, wherein the imaging element is aligned precisely with the first edge of the graft.

5. The prosthesis of claim **1**, wherein the imaging element is aligned precisely with the second edge of the graft.

6. The prosthesis of claim **5**, wherein the proximal end of the stent extends beyond the proximal end of the graft.

7. The prosthesis of claim **2** wherein the suture bore is spaced distally of the imaging element.

8. A stent-graft comprising:

a graft, at least a portion of which is tubular, having a first end, a second end, a first edge having a periphery, and a second edge having a periphery;

a stent having a first end and a second end, wherein the first end is attached to the graft and adjacent to the first edge of the graft, and wherein the first end comprises a plurality of apices;

a plurality of imaging elements affixed to the stent, such that at least two of the plurality of apices has an imaging element affixed thereto;

wherein the plurality of imaging elements is disposed about the periphery of and precisely aligned with the first edge of the graft such that the location of the imaging elements corresponds precisely with the periphery and the first edge of the graft thereby providing precise imaging of the first edge of the graft about the periphery; and

where each imaging element has an area that overlaps the graft.

9. The stent graft of claim **8**, wherein an imaging element of the plurality of imaging elements is affixed to each of the plurality of apices.

10. The stent graft of claim **8**, wherein the stent comprises a plurality of imaging bores in the apices of the stent, wherein each of the imaging bores has a luminal opening and an abluminal opening and the imaging elements are disposed within the imaging bores.

11. The stent graft of claim **8**, wherein the first edge of the graft is a proximal edge of the graft and the imaging elements are disposed at the proximal edge of the graft.

12. The stent graft of claim **8**, wherein the first edge of the graft is a distal edge of the graft and the imaging elements are disposed at the distal edge of the graft.

13. A stent-graft comprising:

a graft, at least a portion of which is tubular, having a first end, a second end, a first opening, a second opening, a lumen defined between the first and second openings,

a first peripheral edge about the first opening defining a terminal end of the graft,

a second peripheral edge about the second opening defining a terminal end of the graft;

a stent attached to the graft and having a first end and a second end, at least the first end comprising a plurality of apices each having a luminal side and an abluminal side, and having an imaging bore extending through the apices from the luminal side to the abluminal side;

an imaging element disposed within each of the imaging bores, the imaging element comprising a material having greater visualization under imaging techniques than a material of the stent, and each imaging element being visible from both the luminal side and the abluminal side of the apices;

wherein each imaging element has an area and is aligned precisely with a peripheral edge of the graft such that the location of the imaging element corresponds precisely with the peripheral edge of the graft with which it is aligned thereby providing precise imaging of the peripheral edge, and

wherein the imaging element has an area and the area overlaps the edge of the graft.

14. The stent graft of claim **13**, wherein the imaging elements are disposed at the proximal edge of the graft.

15. The stent graft of claim **13**, wherein the imaging elements are disposed at the distal edge of the graft.

16. The stent graft of claim **13**, further comprising an attachment bore in each of the apices adjacent to the imaging bore.

17. The stent graft of claim **16** where the attachment bores are disposed inwardly of an edge of the graft.

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